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(71) Applicant (for all designated States except US): DATASCOPE INVESTMENT CORP. [US/US]; 14 Philips Parkay, Montvale, NJ 07645 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LESCHINSKY, Boris [RU/US]; 30 West Saddle River Road, Waldwick, NJ 07643 (US). AHARI, Frederick [US/US]; 16331 Bay Vista Drive, Clearwater, FL 34620 (US).

(74) Agent: RONAI, Abraham; Datascope Corp., 14 Philips Parkway, Montvale, NJ 07645 (US).

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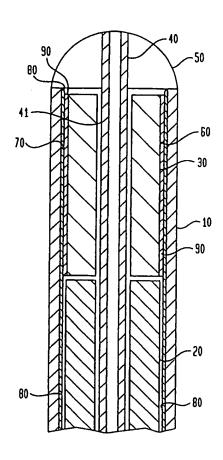
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(54) Title: REDUCED FRICTION GRAFT AND STENT/GRAFT DEPLOYMENT CATHETER

(57) Abstract

A low friction stent/graft (30) deployment catheter comprising a low friction graft having an outer coating (90) of a biocompatible lubricous material, such as Dow Corning's medical silicone (360), and a delivery sheath (42) having an inner coating (80) of a biocompatible lubricous material, such as Dow Corning's MDX4-4159.



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<u>TITLE:</u> REDUCED FRICTION GRAFT AND STENT/GRAFT DEPLOYMENT CATHETER

BACKGROUND OF THE INVENTION

10 1. Field of the Invention

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The invention relates to a graft and a stent/graft deployment catheter, particularly for repairing defects in arteries and other lumens within the body. More particularly, the invention relates to a reduced friction stent/graft deployment catheter for delivering a reduced friction graft in situ for repairing defective body lumens, and particularly abdominal aortic aneurysms.

2. Description of the Prior Art

An abdominal aortic aneurysm (AAA) is a sac caused by an abnormal dilatation of the wall of the aorta as it passes through the abdomen. The aorta is the main artery of the body, supplying blood to all organs and parts of the body except the lungs. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen, and finally divides into the iliac arteries which supply blood to the pelvis and lower extremities.

The AAA ordinarily occurs in the portion of the aorta below the kidneys. When left untreated, the aneurysm will eventually cause the sac to rupture with ensuing fatal hemorrhaging in a very short time. The repair of abdominal aortic aneurysms has typically required major abdominal surgery in which the diseased and aneurysmal segment of the aorta is bridged with a prosthetic device, such as a synthetic

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As with all major surgeries, there are many disadvantages to the above mentioned surgical technique, the foremost of which is the high mortality and morbidity rate associated with surgical intervention of this magnitude. Other disadvantages of conventional surgical repair include the extensive recovery period associated with such surgery; difficulties in suturing the graft to the aorta; the unsuitability of the surgery for many patients, particularly older patients exhibiting comorbid conditions; and the problems associated with performing the surgical procedure on an emergency basis after the aneurysm has already ruptured.

In view of the above mentioned disadvantages of conventional surgical repair techniques, techniques have been developed for repairing AAAs by intraluminally delivering an aortic graft to the aneurysm site through the use of a catheter based delivery system, and securing the graft within the aorta using an expandable stent. Since the first documented clinical application of this technique was reported by Parodi et al. in the Annals of Vascular Surgery, Volume 5, pages 491-499 (1991), the technique has gained more widespread recognition and is being used more commonly. As vascular surgeons have become more experienced with this endovascular technique, however, certain problems have been encountered. One major problem involves deployment of the stent/graft. Substantial friction between the outer surface of the graft material and the inner surface of the delivery sheath of the deployment catheter makes it sometimes difficult to deploy the stent/graft device precisely in the right location while not exerting significant forces which may damage the stent/graft device. The traditional expandable stent/graft is radially

compressed before insertion into the delivery sheath. The more the stent/graft device can be compressed the smaller the introducer sheath and the catheter can be made. Therefore, a highly compressible stent/graft is desired. One problem with radially compressing a given stent/graft to its maximum extent is that once the compressed stent/graft is inserted into the delivery sheath of the catheter, friction between the outer surface of the graft and the inner surface of the delivery sheath, caused by the restoring force of the compressed stent/graft, makes it very difficult to push the stent/graft out of the delivery sheath of the catheter, and therefore, makes it difficult to accurately deploy the stent/graft without damaging it. In light of this design limitation, the total cross sectional area of a traditional expandable stent/graft in its compressed deployment state is generally designed 10% to 30% less than the area of the corresponding delivery sheath in order to limit friction between the graft and the delivery sheath and to ensure that the stent/graft is Therefore, it is desired to not damaged upon deployment. reduce the friction between the graft and the delivery sheath so as to allow for the use of a reduced diameter introducer sheath and deployment catheter.

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The need exists for an improved graft and stent/graft deployment catheter which will overcome the foregoing friction deficiencies of the prior art. More particularly, there exists a need for an improved low friction graft and stent/graft deployment catheter, incorporating a lubricous coating, which will prevent damage to the stent/graft, such as buckling or kinking, during deployment.

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SUMMARY OF THE INVENTION

Accordingly, it is an object of the invention to produce a low friction graft and a low friction stent/graft deployment catheter which is capable of accurately deploying the stent/graft without damaging the stent/graft.

It is another object of the invention to produce a method for packing the low friction stent/graft into the low friction stent/graft deployment catheter.

It is yet another object of the invention to produce a low friction stent/graft deployment catheter which will allow for the use of a smaller introducer sheath and which can be made smaller than similar stent/graft deployment catheters currently on the market without fear of damage to the stent/graft upon deployment.

The invention is a low friction stent/graft deployment catheter comprising a low friction graft having an outer coating of a biocompatible lubricous material, such as Dow Corning's medical silicone 360 (360 is a Dow Corning product identifier), and a delivery sheath having an inner coating of a biocompatible lubricous material, such as Dow Corning's MDX4-4159 (MDX4-4159 is a Dow Corning product identifier).

To the accomplishment of the above and related objects the invention may be embodied in the form illustrated in the accompanying drawings. Attention is called to the fact, however, that the drawings are illustrative only. Variations are contemplated as being part of the invention, limited only by the scope of the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, like elements are depicted by like reference numerals. The drawings are briefly described as follows.

10 FIG 1 is longitudinal cross section of a distal portion of a prior art stent/graft deployment catheter.

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FIG 2 is longitudinal cross section of distal portion of an improved low friction stent/graft deployment catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG 1 illustrates a longitudinal cross section of a coaxial prior art stent/graft deployment catheter. catheter is comprised of a catheter body 10, a tip 50, an inner tube 40, a stent/graft 30, and a plunger 20, all of which are co-axial and have proximal and distal ends. Only a distal portion of the deployment catheter is shown for clarity. The catheter body 10 has an inner surface 70 and is slidingly disposed about the inner tube 40. The plunger 20 is slidingly disposed about the inner tube 40 and is slidingly disposed within the catheter body 10. The distal end of the inner tube 40 is attached to the tip 50. The stent/graft 30 is slidingly disposed about the inner tube 40 and within the catheter body 10 and is between the proximal end of the tip 50 and the distal end of the plunger 20. The stent/graft 30 has an outer surface 60 and a lumen 52 extending from its proximal end to its distal end. The stent/graft lumen 52 is occupied by a distal portion 41 of the inner tube 40.

The stent/graft deployment catheter is inserted percutaneously or via a surgical cut-down method into a blood

vessel. Upon proper positioning of the tip 50 in the blood vessel the plunger 20 is held in place and the catheter body 10 is pulled away from the tip 50 exposing the entire stent/graft 30 to patient's blood. Upon contact with blood the stent/graft 30 expands such that the diameter of the stent/graft lumen 52 is larger than the diameter of the tip 50. The expanded stent/graft 30 becomes fixed in place in the blood vessel and thus bridges the aneurysm. The inner tube 40 is then pulled away from the stent/graft 30 such that the tip 50 passes through the lumen 52 of the stent/graft 30.

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Finally, the deployment catheter is removed from the patient. As discussed above, friction between the catheter body 10 and the stent/graft 30 may require the surgeon to apply a great deal of longitudinal force to the plunger 20, to force the stent/graft out of the deployment catheter, which may damage the stent/graft 30.

FIG 2 illustrates a longitudinal cross section of an improved stent/graft deployment catheter. Only a distal portion of the deployment catheter is shown for clarity. The improved stent/graft deployment catheter is physically identical to the prior art catheter except for the presence of two lubricous coatings. A first coating 80 of a biocompatible lubricous material, such as Dow Corning's MDX4-4159 (MDX4-4159 is a Dow Corning product identifier), is applied to the inner surface 70 of the catheter body 10. A second coating 90 of a biocompatible lubricous material, such as Dow Corning's medical silicone 360 (360 is a Dow Corning product identifier), is applied to the outer surface 60 of the stent/graft 30. The stent/graft 30 is radially compressed to its maximum extent without fear that an increased stent/graft restorative force will increase friction between the inner

surface 70 of the catheter body 10 and the outer surface 60 of the stent/graft 30. Accordingly, the entire deployment catheter can be made smaller than the prior art deployment catheter. Note that the use of a single coating, either on the stent/graft 30 or on the catheter body 10, is contemplated.

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Optimum results are achieved when the inner surface 70 of the catheter body 10 is coated twice with 5% MDX4-4159 solution, and the outer surface of the stent/graft 30 is coated with Dow Corning's medical silicone 360. The stent/graft deployment catheter is packed with the stent/graft 30 in the following manner. First, the inner surface 70 of the catheter body 10 is coated with MDX4-4159. Next, the stent/graft 30 is lubricated with Dow Corning's medical silicone 360. The stent/graft 30 is then compressed radially and is disposed about the distal portion 41 of the inner tube 40 and within the delivery sheath portion 42 of the catheter body 10.

CLAIMS

What is claimed is:

- 1.A catheter deployment device comprising a catheter body and a deployable device held by said catheter body, a lubricous material lies between the catheter body and the deployable device.
- 2. The catheter deployment device as claimed in claim 1 wherein the lubricous material comprises a coating of MDX4-4159 on the catheter body.
- 3. The catheter deployment device as claimed in claim 1 wherein the lubricous material comprises a Dow Corning medical silicone 360 coating on the outer surface of the deployable body.
- 4. The catheter deployment device as claimed in claim 1 wherein the lubricous material comprises a coating of MDX4-4159 on the catheter body and a Dow Corning medical silicone 360 coating on the outer surface of the deployable body.
- 5. The catheter deployment device as claimed in claim 1 wherein the deployable body is a stent/graft.
- 6.A catheter deployment device comprising a catheter body having a lubricous coating and a deployable body, the deployable body is held by the deployment catheter, and the lubricous coating lies between the catheter body and the deployable body.

7.A catheter deployment device comprising a catheter body and a deployable body having a lubricous coating, the deployable body is held by the catheter body, and the lubricous coating lies between the catheter body and the deployable body.

- 8. The catheter deployment device as claimed in claim 7 wherein the lubricous coating on the deployable body is Dow Corning medical silicone 360.
- 9. The catheter deployment device as claimed in claim 6 wherein the lubricous coating on the catheter body is MDX4-4159.
- 10.A stent/graft deployment catheter comprising a catheter body having an inner surface, a plunger, an inner tube, a tip, and a stent/graft having an outer surface, the catheter body, plunger, inner tube, tip, and stent graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end of the plunger and the proximal end of the tip, the inner surface of the catheter body is coated with a first lubricous material.
- 11. The stent/graft deployment catheter as claimed in claim 10 wherein the first lubricous material is MDX4-4159.
- 12. The stent/graft deployment catheter as claimed in claim 10 wherein the outer surface of the stent/graft is coated with a second lubricous material.

13. The stent/graft deployment catheter as claimed in claim 12 wherein the second lubricous material is Dow Corning medical silicone 360.

- 14.A graft having an outer surface coated with a lubricous material.
- 15. The graft as claimed in claim 14 wherein the lubricous material is Dow Corning medical silicone 360.
- 16.A method for packing a stent/graft deployment catheter comprising a catheter body having an inner surface, a plunger, an inner tube, a tip, and a tubular stent/graft having an outer surface, the catheter body, plunger, inner tube, tip, and stent graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end of the plunger and the proximal end of the tip, comprising the steps of:
- a) lubricating the inner surface of the catheter body with a first lubricous material;
- b) radially compressing the stent/graft; and
- c) disposing the compressed stent/graft about the distal end of the inner tube and within the distal end of the catheter body.
- 17. The method for packing a stent/graft deployment catheter as a claimed in claim 16 wherein the first lubricous material is MDX4-4159.

18.A method for packing a stent/graft deployment catheter comprising a catheter body having an inner surface, a plunger, an inner tube, a tip, and a tubular stent/graft having an outer surface, the catheter body, plunger, inner tube, tip, and stent graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end of the plunger and the proximal end of the tip, comprising the steps of:

a) lubricating the outer surface of the stent/graft with a

- a) lubricating the outer surface of the stent/graft with a first lubricous material;
- b) radially compressing the stent/graft; and
- c) disposing the compressed stent/graft about the distal end of the inner tube and within the distal end of the catheter body.
- 19. The method for packing a stent/graft deployment catheter as claimed in claim 18 wherein the first lubricous material is Dow Corning medical silicone 360.
- 20. The method as claimed in claim 18 wherein the method further comprises the step of lubricating the inner surface of the catheter body with a second lubricous material before radially compressing the stent/graft.
- 21. The method as claimed in claim 20 wherein the second lubricous material is MDX4-4159 and the first lubricous material is Dow Corning medical silicone 360.

AMENDED CLAIMS

[received by the International Bureau on 5 August 1999 (05.08.99); original claims 3, 4, 6-9 and 12-21 cancelled; original claims 1, 2, 5, 10 and 11 amended; new claims 22-35 added (9 pages)]

What is claimed is:

- 1. A catheter deployment device comprising a catheter body having a lubricious inner surface, a self-expanding deployable device disposed within said catheter body, and a lubricous material between the lubricious inner surface of the catheter body and an outer surface of the deployable device, said lubricious material being in a liquid state prior to insertion in a vessel and while in said vessel.
- 2. The catheter deployment device as claimed in claim 1 wherein the lubricous material is an amino functional silicone oligomer.
- 3. (Canceled) The catheter deployment device as claimed in claim 1 wherein the lubricous material comprises a Dow Corning medical silicone 360 coating on the outer surface of the deployable body.
- 4. (Canceled) The catheter deployment device as claimed in claim 1 wherein the lubricous material comprises a coating of MDX4-4159 on the catheter body and a Dow Corning medical silicone 360 coating on the outer surface of the deployable body.
- 5. The catheter deployment device as claimed in claim 1 wherein the deployable device is a stent/graft.
- 6. (Canceled) A catheter deployment device comprising a catheter body having a lubricous coating and a deployable

body, the deployable body is held by the deployment catheter, and the lubricous coating lies between the catheter body and the deployable body.

- 7. (Canceled) A catheter deployment device comprising a catheter body and a deployable body having a lubricous coating, the deployable body is held by the catheter body, and the lubricous coating lies between the catheter body and the deployable body.
- 8. (Canceled) The catheter deployment device as claimed in claim 7 wherein the lubricous coating on the deployable body is Dow Corning medical silicone 360.
- 9. (Canceled) The catheter deployment device as claimed in claim 6 wherein the lubricous coating on the catheter body is MDX4-4159.
- 10. A stent/graft deployment catheter comprising a catheter body having a lubricous inner surface, a plunger, an inner tube, a tip, a stent/graft having an outer surface, and a lubricous material between the lubricous inner surface of the catheter body and the outer surface of the stent/graft, said lubricious material being in a liquid state prior to insertion in a vessel and while in said vessel, the catheter body, plunger, inner tube, tip, and stent/graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end

of the plunger and the proximal end of the tip.

- 11. The stent/graft deployment catheter as claimed in claim 10 wherein the lubricous material is an amino functional silicone oligomer.
- 12. (Canceled) The stent/graft deployment catheter as claimed in claim 10 wherein the outer surface of the stent/graft is coated with a second lubricous material.
- 13. (Canceled) The stent/graft deployment catheter as claimed in claim 12 wherein the second lubricous material is Dow Corning medical silicone 360.
- 14. (Canceled) A graft having an outer surface coated with a lubricous material.
- 15. (Canceled) The graft as claimed in claim 14 wherein the lubricous material is Dow Corning medical silicone 360.
- 16. (Canceled) A method for packing a stent/graft deployment catheter comprising a catheter body having an inner surface, a plunger, an inner tube, a tip, and a tubular stent/graft having an outer surface, the catheter body, plunger, inner tube, tip, and stent graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end of the plunger and the proximal end of the tip, comprising the steps of:

a) lubricating the inner surface of the catheter body with a first lubricous material;

- b) radially compressing the stent/graft; and
- c) disposing the compressed stent/graft about the distal end of the inner tube and within the distal end of the catheter body.
- 17. (Canceled) The method for packing a stent/graft deployment catheter as a claimed in claim 16 wherein the first lubricous material is MDX4-4159.
- 18. (Canceled) A method for packing a stent/graft deployment catheter comprising a catheter body having an inner surface, a plunger, an inner tube, a tip, and a tubular stent/graft having an outer surface, the catheter body, plunger, inner tube, tip, and stent graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the stent/graft lies between the distal end of the plunger and the proximal end of the tip, comprising the steps of:

 a) lubricating the outer surface of the stent/graft with a
- first lubricous material;
- b) radially compressing the stent/graft; and
- c) disposing the compressed stent/graft about the distal end of the inner tube and within the distal end of the catheter body.
- 19. (Canceled) The method for packing a stent/graft deployment catheter as claimed in claim 18 wherein the first lubricous material is Dow Corning medical silicone 360.

20. (Canceled) The method as claimed in claim 18 wherein the method further comprises the step of lubricating the inner surface of the catheter body with a second lubricous material before radially compressing the stent/graft.

- 21. (Canceled) The method as claimed in claim 20 wherein the second lubricous material is MDX4-4159 and the first lubricous material is Dow Corning medical silicone 360.
- 22. A method for deploying a stent/graft loaded into a stent/graft delivery system, said stent/graft delivery system comprising a catheter having a lubricious inner surface, a plunger disposed within said catheter, and a lubricious material between the lubricious inner surface of the catheter and an outer surface of the stent/graft, said lubricious material being in a liquid state prior to insertion in a vessel and while in said vessel, comprising the step of moving the catheter and plunger relative to each other thereby exposing the stent/graft.
- 23. A method for packing a self-expanding deployable device into a catheter delivery system having a lubricious inner surface, comprising the steps of:
- a) applying a lubricous material to an outer surface of the deployable device, said lubricious material being in a liquid state prior to insertion into a vessel and while in said vessel;
- b)radially compressing the deployable device; and c)advancing said deployable device into the catheter delivery system.

24. A method for packing a self-expanding deployable device into a catheter delivery system having a lubricious inner surface, comprising the steps of:

- a) applying a lubricous material to the lubricious inner surface of the catheter delivery system, said lubricious material being in a liquid state prior to insertion into a vessel and while in said vessel;
- b) radially compressing the deployable device; andc) advancing said deployable device into the catheter delivery system.
- 25. A catheter deployment device comprising a catheter body having a lubricious inner surface, a radially compressed self-expanding deployable device disposed within said catheter body, and a lubricous material between the lubricious inner surface of the catheter body and an_outer surface of the deployable device, said lubricious material allowing the deployable device to be radially compressed further than without said lubricious material while still allowing for deployment.
- 26. The catheter deployment device as claimed in claim 25 wherein the lubricious material is an amino functional silicone oligomer.
- 27. The catheter deployment device as claimed in claim 25 wherein the deployable device is radially compressed such that the total cross sectional area occupied by the material making up the deployable device is less than 10% smaller than the cross sectional area of a portion of the catheter body in which the deployable body is disposed.

28. A stent/graft deployment catheter comprising a catheter body having a lubricious inner surface, a plunger, an inner tube, a tip, a stent/graft having an outer surface, and a lubricous material between the lubricious inner surface of the catheter body and the outer surface of the stent/graft, the catheter body, plunger, inner tube, tip, and stent/graft, have distal and proximal ends and are co-axial, the catheter body, the plunger, and the stent/graft are slidingly disposed about the inner tube, the plunger is disposed within the catheter body, the proximal end of the tip is attached to the distal end of the catheter body, the radially compressed stent/graft lies between the distal end of the plunger and the proximal end of the tip, said lubricious material allowing the stent/graft to be radially compressed further than without said lubricious material while still allowing for deployment.

- 29. The catheter deployment device as claimed in claim 28 wherein the lubricious material is an amino functional silicone oligomer.
- 30. The catheter deployment device as claimed in claim 29 wherein the stent/graft is radially compressed such that the total cross sectional area occupied by the material making up the stent/graft is less than 10% smaller than the cross sectional area of a portion of the catheter body in which the deployable body is disposed.
- 31. A method for deploying a radially compressed stent/graft loaded into a stent/graft delivery system, said stent/graft delivery system comprising a catheter having a lubricious inner surface, a plunger disposed within said catheter, and a

lubricious material between the lubricious inner surface of the catheter and an outer surface of the stent/graft, said lubricious material allowing the stent/graft to be radially compressed further than without said lubricious material while still allowing for deployment, comprising the step of moving the catheter and plunger relative to each other thereby exposing the stent/graft.

- 32. The method as claimed in claim 31 wherein said stent/graft is radially compressed such that the total cross sectional area occupied by the material making up the deployable device is less than 10% smaller than the cross sectional area of a portion of the catheter body in which the deployable body is disposed.
- 33. A method for packing a self-expanding deployable device into a catheter delivery system having a lubricious inner surface, comprising the steps of:
- a) applying a lubricous material to an outer surface of the deployable device;
- b) radially compressing the deployable device, said lubricious material allowing the deployable device to be radially compressed further than without said lubricious material while still allowing for deployment; and
- c) advancing said deployable device into the catheter delivery system.
- 34. A method for packing a self-expanding deployable device into a catheter delivery system having a lubricious inner surface, comprising the steps of:
- a) applying a lubricous material to the lubricious inner

surface of the catheter delivery system;

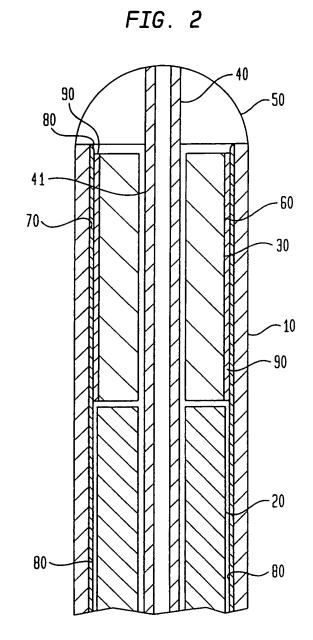
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b) radially compressing the deployable device, said lubricious material allowing the deployable device to be radially compressed further than without said lubricious material while still allowing for deployment; and

- c) advancing said deployable device into the catheter delivery system.
- 35. The method as claimed in claim 34 wherein the deployable device is compressed such that the total cross sectional area occupied by the material making up the deployable device is less than 10% smaller than the cross sectional area of a portion of the catheter delivery system in which the deployable device is disposed.

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FIG. 1 (PRIOR ART) - 40 -52 41--60 70、 - 30 42--10 -20 43-



INTERNATIONAL SEARCH REPORT

International application No. PCT/US99/07125

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) :A61B 17/00 US CL :606/108, 198; 623/1, 12 According to International Patent Classification (IPC) or to both national classification and IPC									
B. FIELDS SEARCHED									
Minimum documentation searched (classification system followed by classification symbols) U.S.: 606/108, 198; 623/1, 12									
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched									
Electronic data base consulted during the international search (name of data base and, where practicable,	search terms used)							
C. DOCUMENTS CONSIDERED TO BE RELEVANT									
Category* Citation of document, with indication, where a	appropriate, of the relevant passages	Relevant to claim No.							
X US 5,690,644 A (YUREK et al.) 25 37-43.	November 1997, col. 5 lines	1, 2, 5, 6, 9-11, 16, 17							
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Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: "T" document defining the general state of the art which is not considered "T" document defining the general state of the art which is not considered									
to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	y" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family								
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